Indiana Food, Drug, and Cosmetic Act

INDIANA STATE BOARD OF HEALTH
Indianapolis

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Indiana Food, Drug, and Cosmetic Act

Enacted March 6, 1939
Chapter 38, Acts 1939

AN ACT concerning food, drugs, devices, and cosmetics and repealing all laws in conflict therewith.

Section 1. Be it enacted by the General Assembly of the State of Indiana, That this Act may be cited as the "Uniform Indiana Food, Drug, and Cosmetic Act."

Sec. 2. Legislative Intent. This Act is intended to enact State Legislation—

(a) Which safeguards the public health and promotes the public welfare by protecting the consuming public from injury by product use and the purchasing public from injury by merchandising deceit, flowing from intrastate commerce in food, drugs, devices, and cosmetics; and

(b) Which is uniform, as provided in this Act, with the Federal Food, Drug, and Cosmetic Act; and with the Federal Trade Commission Act, to the extent it expressly outlaws the false advertisement of food, drugs, devices, and cosmetics; and

(c) Which thus promotes uniformity of such laws and their administration and enforcement, in and throughout the United States.

Sec. 3. Definitions. For the purposes of this Act—

(a) The term "Federal Act" means the Federal Food, Drug, and Cosmetic Act (Title 21 U. S. C. 301 et. seq.; 52 Stat. 1040 et seq.) and amendments thereto.

(b) The term "intrastate commerce" means any and all commerce within the State of Indiana and subject to the jurisdiction thereof; and includes the operation of any business or service establishment.

(c) The term "sale" means any and every sale and includes (1) manufacture, processing, transporting, handling, packing, canning, bottling, or any other production, preparation, or putting up; (2) exposure, offer, or any other proffer; (3) holding, storing, or any other possession; (4) dispensing, giving, delivering, serving, or any other supplying; and (5) applying, administering, or any other using.

(d) The term "Secretary" means the Secretary of the Indiana State Board of Health.

(e) The term "person" includes individual partnership, corporation, and association.

(f) The term "food" means (1) articles used for food or drink for man, (2) chewing gum, and (3) articles used for components of any such article.

(g) The term "drug" means (1) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (3) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (4) articles intended for use as a component of any article specified in clause (1), (2), or (3); but does not include devices or their components, parts, or accessories.

(h) The term "device" (except when used in paragraph (n) of this section and in sections 4 (h), 13 (f), 18 (c), and 22 (c)) means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or (2) to affect the structure or any function of the body of man or other animals.

(i) The term "cosmetic" means (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap.

(j) The term "official compendium" means the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, official National Formulary, or any supplement to any of them.

(k) The term "label" means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this Act that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.

(l) The term "immediate container" does not include package liners.

(m) The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

(n) If an article is alleged to be misbranded because the labeling is misleading, or if an advertisement is alleged to be false because it is misleading, then in determining whether the labeling or advertisement is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, sound, or any combination thereof, but also the extent to which the labeling or advertisement fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertisement relates under the conditions of use prescribed in the labeling or advertisement thereof or under such conditions of use as are customary or usual.

(o) The representation of a drug, in its labeling or advertisement, as an antiseptic shall be considered to be a representation that it is a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body.

(p) The term "new drug" means (1) any drug the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of drugs, as safe for use under the conditions prescribed, recommended, or suggested in the labeling thereof; or (2) any drug the composition of which is such that such drug, as a result of investigations to determine its safety for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

(q) The term "advertisement" means all representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or which are likely to induce, directly or indirectly, the purchase of food, drugs, devices, or cosmetics.

(r) The term "contaminated with filth" applies to any food, drug, device, or cosmetic not securely protected from dust, dirt, and as far as may be necessary by all reasonable means, from all foreign or injurious contaminations.

(s) The term "Board" means the Indiana State Board of Health.

Sec. 4. Prohibited Acts. The following acts and the causing thereof are hereby prohibited:

(a) The sale in intrastate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.

(b) The adulteration or misbranding of any food, drug, device, or cosmetic in intrastate commerce.

(c) The receipt in intrastate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the sale thereof in such commerce for pay or otherwise.

(d) The sale of any article in violation of sections 14 and 20.

(e) The dissemination of any false advertisement.

(f) The refusal to permit access to or copying of any record as required by section 28.

(g) The refusal to permit entry or inspection and collecting samples as authorized by sections 27 and 29.

(h) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label, or other identification device authorized or required by regulations promulgated under the provisions of this Act.

(i) The using by any person to his own advantage, or revealing, other than to the Secretary or duly authorized representative, or to the courts when relevant in any judicial proceeding under this Act, any information acquired under authority of section 20 or 29 concerning any method or process which as a trade secret is entitled to protection.

(j) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale and results in such article being misbranded.

(k) The using, on the labeling of any drug or in any advertising relating to such drug, of any representation or suggestion that an application with respect to such drug is effective under section 20, or that such drug complies with the provisions of such section.

(l) The removal or disposal of a quarantined article in violation of section 7.

(m) The giving of a guaranty or undertaking in intrastate commerce, referred to in section 6 (c) that is false.

Sec. 5. Injunction Proceedings. In addition to the remedies hereinafter provided, the Secretary is hereby authorized to apply to the proper circuit or superior court for, and such

court shall have jurisdiction upon hearing and for cause shown, to grant a temporary or permanent injunction restraining any person from violating any provision of section 4; irrespective of whether or not there exists an adequate remedy at law.

Sec. 6. Penalties—Guaranty. (a) Any person who violates any of the provisions of section 4 shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment in the county jail for not more than six months or a fine of not less than $10.00 nor more than $1,000.00, or both such imprisonment and fine; and for the second or subsequent offense shall be subject to imprisonment in the state prison for not more than two years, or a fine of not less than $50.00 nor more than $2,000.00, or both such imprisonment and fine.

(b) Notwithstanding the provisions of subsection (a) of this section, in case of a violation of any provision of section 4, with intent to defraud or mislead, the penalty shall be imprisonment in the state prison for not more than two years, or a fine of not less than $50.00 nor more than $2,000.00, or both such imprisonment and fine.

(c) No person shall be subject to the penalties of subsection (a) of this section, for having violated section 4 (a) or (c) if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the article, to the effect that such article is not adulterated or misbranded within the meaning of this Act or the Federal Act.

(d) No publisher, radio-broadcast licensee, advertising agency, or agency or medium for the dissemination of advertising, except the manufacturer, packer, distributor, or seller of the article to which the advertisement relates, shall be subject to the penalties of subsection (a) of this section by reason of his dissemination of any false advertisement, unless he has refused on the request of the Secretary to furnish the name and address of the manufacturer, packer, distributor, seller, or advertising agency in the United States, who caused him to disseminate such false advertisement.

(e) No person shall be subject to the penalties of subsections (a) or (b) of this section if such person has been acquitted or convicted under the Federal Act of the same act or omission which, it is alleged, constitutes a violation of this Act.

Sec. 7. Seizure. (a) Whenever a duly authorized agent of the Board finds, or has probable cause to believe, that any food, drug, device, or cosmetic is adulterated, or so misbranded

as to be dangerous or fraudulent, within the meaning of this Act, he shall affix to such article a tag or other appropriate marking, giving notice that such article is, or is suspected of being, adulterated or misbranded and has been detained or embargoed for a period of five days in the case of food and for a period of ten days in the case of drugs and cosmetics, and warning all persons not to remove or dispose of such article by sale or otherwise until permission for removal or disposal is given by such agent or the court. It shall be unlawful for any person to remove or dispose of such detained or embargoed article by sale or otherwise without such permission. The claimant shall be authorized to destroy the article so detained if such article is destroyed under the supervision of an agent of the Board.

(b) When an article detained or embargoed under subsection (a) has been found by such agent to be adulterated, or misbranded, he shall within five days thereafter file his petition in any circuit or superior court or before the judge thereof in vacation in whose jurisdiction the article is detained or embargoed for a libel for condemnation of such article. When such agent has found that an article so detained or embargoed is not adulterated or misbranded, he shall remove the tag or other marking.

(c) If the court finds that a detained or embargoed article is adulterated or misbranded, such article shall, after entry of the decree, be destroyed at the expense of the claimant thereof, under the supervision of such agent; and all court costs and fees, and storage and other proper expenses, shall be taxed against the claimant of such article or his agent: Provided, That when the adulteration or misbranding can be corrected by proper labeling or processing of the article, the court, after entry of the decree and after such costs, fees, and expenses have been paid and a good and sufficient bond, conditioned that such article shall be so labeled or processed, has been executed, may by order direct that such article be delivered to the claimant thereof for such labeling or processing under the supervision of an agent of the Board. The expense of such supervision shall be paid by the claimant. Such bond shall be returned to the claimant of the article on representation to the court by the Secretary that the article is no longer in violation of this Act, and that the expenses of such supervision have been paid.

(d) Whenever the Secretary or any of his duly authorized agents shall find in any room, building, vehicle of transportation, or other structure, or on any premises, any dairy product, meat, meat product, seafood, poultry, confectionery, bakery product, vegetable, fruit or other perishable articles which are unsound, or contain any filthy, decomposed, or putrid

substance, or that may be poisonous or deleterious to health or otherwise unsafe, the same being hereby declared to be a nuisance, the Secretary, or his authorized agent, shall forthwith condemn or destroy the same, or in any other manner render the same unsalable as human food.

Sec. 8. Duty of Attorney—Hearing Before Report of Criminal Violation. (a) It shall be the duty of each prosecuting attorney to whom the Secretary or his authorized agent reports any violation of this Act, to cause appropriate proceedings to be instituted in the proper court, without delay, and to be duly prosecuted as prescribed by law.

(b) Before any violation of this Act is reported by the Secretary or his authorized agent to any such attorney for the institution of a criminal proceeding, the person against whom such proceeding is contemplated shall be given appropriate notice and an opportunity to present his views to the Secretary or his authorized agent, either orally or in writing, with regard to such contemplated proceeding.

Sec. 9. Report of Minor Violations. Nothing in this Act shall be construed as requiring the Secretary or his authorized agent to report for the institution of proceedings under this Act, minor violations of this Act, whenever he believes that the public interest will be adequately served in the circumstances by a suitable written notice or warning.

Sec. 10. Proceedings in Name of State. All such proceedings for the enforcement, or to restrain violations, of this Act shall be by and in the name of the State of Indiana.

Sec. 11. Definitions and Standards for Food. Whenever any definitions or standard of identity, quality or fill of container for any food or class of food are promulgated under section 401 of the Federal Act or the Federal Meat Inspection Act of 1907, as amended, the Board shall promptly, and without a hearing, promulgate said definitions and standard for Indiana. Whenever, with regard to any other food or class of food, the Board shall find that such action will promote honesty and fair dealing in the interest of consumers, the Board shall promulgate regulations fixing and establishing for any such food or class of food a reasonable definition and standard of identity, and a reasonable standard of quality and fill of container. In prescribing a definition and standard of identity for any such food or class of food in which optional ingredients are permitted, the Board shall, for the purpose of promoting honesty and fair dealing in the interest of consumers, designate the optional ingredients which shall be named on the label.

Sec. 12. Adulterated Foods. A food shall be deemed to be adulterated—

(a) (1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or (2) if it bears or contains any added poisonous or added deleterious substance which is unsafe within the meaning of section 16; or (3) if it consists in whole or in part of a diseased, contaminated, filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or (4) if it has been produced, transported, handled, prepared, packed, or held under insanitary conditions or in insanitary containers whereby it may have become contaminated with filth, or whereby it may have been rendered diseased, unwholesome, or injurious to health; or (5) if it is in whole or in part the product of a diseased animal or of an animal which has died otherwise than by slaughter, or that has been fed upon the uncooked offal from a slaughterhouse; or (6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.

(b) (1) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or (2) if any substance has been substituted wholly or in part therefor; or (3) if damage or inferiority has been concealed in any manner; or (4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is or create a deceptive appearance: Provided, That clauses (1) and (2) of this subdivision (b) shall not prohibit the removal of butterfat from or the addition of skim milk to dairy products which comply with definitions and standards for such products as adopted by the Board.

(c) If it bears or contains a coal-tar color other than one from a batch which has been certified by the United States Department of Agriculture, as provided by regulations promulgated under section 406 (b) of the Federal Act.

(d) If it is confectionery and it bears or contains any alcohol or nonnutritive article or substance except harmless coloring, harmless flavoring, harmless resinous glaze not in excess of four-tenths of 1 per centum, harmless natural gum, and pectin: Provided, That this paragraph shall not apply to any confectionery by reason of its containing less than one-half of 1 per centum by volume of alcohol derived solely from the use of flavoring extracts, or to any chewing gum by reason of its containing harmless nonnutritive masticatory substances.

(e) If it falls below the standard of purity, quality, or strength which it purports or is represented to possess.

Sec. 13. Misbranded Foods. A food shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular.

(b) If it is offered for sale under the name of another food.

(c) If it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word "imitation" and, immediately thereafter, the name of the food imitated.

(d) If its container is so made, formed, or filled as to be misleading.

(e) If in package form, unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: Provided, That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Board.

(f) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(g) If it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations as provided by section 11, unless (1) it conforms to such definition and standard, and (2) its label bears the name of the food specified in the definition and standard, and, insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food.

(h) If it purports to be or is represented as (1) a food for which a standard of quality has been prescribed by regulations as provided by section 11, and its quality falls below such standard, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard; or (2) a food for which a standard or standards of fill of container have been prescribed by regulation as provided by section 11, and it falls below the standard of fill of container applicable thereto, unless its label bears, in such

manner and form as such regulations specify, a statement that it falls below such standard.

(i) If it is not subject to the provisions of paragraph (g) of this section, unless its label bears (1) the common or usual name of the food, if any there be, and (2) in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient; except that spices, flavorings, and colorings, other than those sold as such, may be designated as spices, flavorings, and colorings without naming each: Provided, That to the extent that compliance with the requirements of clause (2) of this paragraph is impracticable, or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Board.

(j) If it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the Board determines to be, and by regulations prescribes as, necessary in order fully to inform purchasers as to its value for such uses.

(k) If it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact: Provided, That to the extent that compliance with the requirements of this paragraph is impracticable, exemptions shall be established by regulations promulgated by the Board. The provisions of this paragraph and paragraphs (g) and (i) with respect to artificial coloring shall not apply in the case of butter, cheese, or ice cream.

Sec. 14. Registration. Within thirty days after the passage of this Act every manufacturer, processor, repackager or wholesale distributor of food, drugs or cosmetics, who maintains a place of business in this state, shall file with the Board, upon forms to be furnished by the Board, a written statement of the name and address of the owner, the character of the business, and the business address of each such place of business in this state. That no new place of business for the manufacture, processing, repacking or wholesale distribution of food, drugs or cosmetics may be established in this state until it has been registered as herein above provided. That in case of change of ownership of any registered place of business, the new owner shall re-register said place of business before operating the same.

Sec. 15. Exemptions in Case of Food. Food, which is, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at an establishment other than the establishment where it was originally processed or packed, is exempted from the affirmative labeling requirements of this Act, while it is in transit in intra-

state commerce from the one establishment to the other, if such transit is made in good faith for such completion purposes only; but it is otherwise subject to all the applicable provisions of this Act.

Sec. 16. Tolerances for Added Poisonous Ingredients in Food. Any poisonous or deleterious substance added to any food except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice, shall be deemed to be unsafe for purposes of the application of clause (2) of section 12 (a); but when such substance is so required or cannot be so avoided, the Board shall promulgate regulations limiting the quantity therein or thereon to such extent as the Board finds necessary for the protection of public health, and any quantity exceeding the limits so fixed shall also be deemed to be unsafe for purposes of the application of clause (2) of section 12 (a). (While such a regulation is in effect limiting the quantity of any such substances in the case of any food, such food shall not, by reason of bearing or containing any added amount of such substance, be considered to be adulterated within the meaning of clause (1) section 12 (a).) In determining the quantity of such added substance to be tolerated in or on different articles of food, the Board shall take into account the extent to which the use of such substance is required or cannot be avoided in the production of each such article, and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.

Sec. 17. Adulterated Drugs and Devices. A drug or device shall be deemed to be adulterated—

(a) (1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; or (2) if it has been produced, prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (3) if it is a drug and its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (4) if it is a drug and it bears or contains, for purposes of coloring only, a coal-tar color other than one from a batch which has been certified by the United States Department of Agriculture, as provided by regulations promulgated under section 504 of the Federal Act.

(b) If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium. Such determination

as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in such compendium, or in the absence of or inadequacy of such tests or methods of assay, those prescribed by the Secretary of Agriculture of the United States in regulations promulgated under section 501 (b) of the Federal Act. No drug defined in an official compendium shall be deemed to be adulterated under this paragraph because it differs from the standard of strength, quality, or purity therefor set forth in such compendium, if its difference in strength, quality, or purity from such standard is plainly stated on its label. Whenever a drug is recognized in both the United States Pharmacopoeia and the Homeopathic Pharmacopoeia of the United States it shall be subject to the requirements of the United States Pharmacopoeia unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the Homeopathic Pharmacopoeia of the United States and not to those of the United States Pharmacopoeia.

(c) If it is not subject to the provisions of paragraph (b) of this section and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.

(d) If it is a drug and any substance has been (1) mixed or packed therewith so as to reduce its quality or strength or (2) substituted wholly or in part therefor.

Sec. 18. Misbranded Drugs and Devices. A drug or device shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular.

(b) If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: Provided, That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Board.

(c) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(d) If it is for use by man and contains any quantity of the narcotic or hypnotic substance

alpha eucaine	chloral	morphine
barbituric acid	coca	opium
betaeucaine	cocaine	paraldehyde
bromal	codeine	peyote
cannabis	heroin	sulphonmethane
carbromal	marihuana	

or any chemical derivative of such substance, which derivative has been by the Board, after investigation found to be, and by regulations under this Act, or by regulations promulgated by the Secretary of Agriculture of the United States under section 502 (d) of the Federal Act, designated as, habit forming; unless its label bears the name, and quantity or proportion of such substance or derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

(e) If it is a drug and is not designated solely by a name recognized in an official compendium unless its label bears (1) the common or usual name of the drug, if such there be; and (2) in case it is fabricated from two or more ingredients, the common or usual name of each active ingredient, including the kind and quantity or proportion of any alcohol, and also including, whether active or not, the name and quantity or proportion of any

bromides	antipyrine	digitalis glucosides
ether	atropine	mercury
chloroform	hyoscine	ouabain
acetanilid	hyoscyamine	strophanthin
acetphenetidin	arsenic	strychnine
amidopyrine	digitalis	thyroid

or any derivative or preparation of any such substances, contained therein: Provided, That to the extent that compliance with the requirements of clause (2) of this paragraph is impracticable, exemptions shall be established by regulations promulgated by the Board.

(f) Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users: Provided, That where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Board shall promulgate regulations exempting such drug or device from such requirement.

(g) If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein: Provided, That the method

of packing may be modified with the consent of the Board in accordance with regulations promulgated by the Secretary of Agriculture of the United States under section 502 (g) of the Federal Act. Whenever a drug is recognized in both the United States Pharmacopoeia and the Homeopathic Pharmacopoeia of the United States, it shall be subject to the requirements of the United States Pharmacopoeia with respect to packaging and labeling unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the Homeopathic Pharmacopoeia of the United States, and not to those of the United States Pharmacopoeia.

(h) If it has been found by the Secretary of Agriculture of the United States or the Board to be a drug liable to deterioration, unless it is packaged in such form and manner, and its label bears a statement of such precautions, as the Secretary of Agriculture of the United States or the Board shall by regulations require as necessary for the protection of the public health. No such regulation shall be established for any drug recognized in an official compendium until the Secretary of Agriculture of the United States or the Board shall have informed the appropriate body charged with the revision of such compendium of the need for such packaging or labeling requirements and such body shall have failed within a reasonable time to prescribe such requirements.

(i) (1) If it is a drug and its container is so made, formed, or filled as to be misleading; or (2) if it is an imitation of another drug; or (3) if it is offered for sale under the name of another drug.

(j) If it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

Sec. 19. Exemptions in Case of Drugs and Devices. (a) A drug or device which is, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at an establishment other than the establishment where it was originally processed or packed, is exempted from the affirmative labeling and packaging requirements of this Act, while it is in transit in intrastate commerce from the one establishment to the other, if such transit is made in good faith for such completion purposes only; but it is otherwise subject to all the applicable provisions of this Act.

(b) A drug dispensed on a written prescription signed by a physician, dentist, or veterinarian (except a drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail), shall if—

(1) such physician, dentist, or veterinarian is licensed by law to administer such drug, and

(2) such drug bears a label containing the name and place of business of the dispenser, the serial number and date of such prescription, and the name of such physician, dentist, or veterinarian, be exempt from the requirements of section 18.

Sec. 20. New Drugs. (a) No person shall introduce or deliver for introduction into intrastate commerce any new drug unless (1) an application with respect thereto has become effective under section 505 of the Federal Act, or (2) when not subject to the Federal Act unless such drug has been tested and has not been found to be unsafe for use under the conditions prescribed, recommended, or suggested in the labeling thereof, and prior to selling or offering for sale such drug, there has been filed with the Secretary an application setting forth (a) full reports of investigations which have been made to show whether or not such drug is safe for use; (b) a full list of the articles used as components of such drug; (c) a full statement of the composition of such drug; (d) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (e) such samples of such drug and of the articles used as components thereof as the Secretary may require; and (f) specimens of the labeling proposed to be used for such drug.

(b) An application provided for in subsection (a) (2) shall become effective on the sixtieth day after the filing thereof, except that if the Secretary finds after due notice to the applicant and giving him an opportunity for a hearing, that the drug is not safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof, he shall, prior to the effective date of the application, issue an order refusing to permit the application to become effective.

(c) This section shall not apply—

(1) to a drug dispensed on a written prescription signed by a physician, dentist, or veterinarian (except a drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail), if such physician, dentist, or veterinarian is licensed by law to administer such drug, and such drug bears a label containing the name and place of business of the dispenser, the serial number and date of such prescription, and the name of such physician, dentist, or veterinarian; or

(2) to a drug intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety of drugs

provided the drug is plainly labeled "For investigational use only"; or

(3) to a drug sold in this State at any time prior to the enactment of this Act or introduced into interstate commerce at any time prior to the enactment of the Federal Act; or

(4) to a drug which is licensed under the Virus, Serum, and Toxin Act of July 1, 1902 (U. S. C., 1934 ed., title 42, chap. 4.), or the Virus, Serums, Toxins, Antitoxins and Analagous Products Act of March 4, 1913 (U. S. C., 1934 ed., title 21, chap. 5).

(d) An order refusing to permit an application under this section to become effective may be revoked by the Secretary.

Sec. 21. Adulterated Cosmetics. A cosmetic shall be deemed to be adulterated—

(a) It it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual: Provided, That this provision shall not apply to coal-tar hair dye, the label of which bears the following legend conspicuously displayed thereon: "Caution—This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness.", and the labeling of which bears adequate directions for such preliminary testing. For the purposes of this paragraph and paragraph (e) the term "hair dye" shall not include eyelash dyes or eyebrow dyes.

(b) If it consists in whole or in part of any filthy, putrid, or decomposed substance.

(c) If it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

(d) If its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.

(e) [If] it is not a hair dye and it bears or contains a coal-tar color other than one from a batch which has been certified by the United States Department of Agriculture, as provided by regulations promulgated under section 604 of the Federal Act.

Sec. 22. Misbranded Cosmetics. A cosmetic shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular.

(b) If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: Provided, That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Board.

(c) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(d) If its container is so made, formed, or filled as to be misleading.

Sec. 23. Exemptions in Case of Cosmetics. A cosmetic which is, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at an establishment other than the establishment where it was originally processed or packed, is exempted from the affirmative labeling requirements of this Act, while it is in transit in intrastate commerce from the one establishment to the other, if such transit is made in good faith for such completion purposes only; but it is otherwise subject to all the applicable provisions of this Act.

Sec. 24. False Advertisement of Food, Drugs, Devices, and Cosmetics. An advertisement of a food, drug, device, or cosmetic shall be deemed to be false, if it is false or misleading in any particular.

Sec. 25. False Advertisement of Drugs and Devices. The advertisement of a drug or device representing it to have any effect in

albuminuria	cancer	erysipelas
appendicitis	carbuncles	gallstones
arteriosclerosis	cholecystitis	heart and vascular diseases
blood poison	diabetes	high blood pressure
bone disease	diphtheria	
Bright's disease	dropsy	

mastoiditis	poliomyelitis	sinus infection
measles	(infantile paralysis)	smallpox
meningitis	prostate gland disorders	tuberculosis
mumps	pyelitis	tumors
nephritis	scarlet fever	typhoid
otitis media	sexual impotence	uremia
paralysis		venereal disease
pneumonia		

shall also be deemed to be false; except that no advertisement not in violation of section 24 shall be deemed to be false under section 25 if it is disseminated only to members of the medical, dental, pharmacal, and other legally recognized professions dealing with the healing arts, or appears only in the scientific periodicals of these professions, or is disseminated only for the purpose of public-health education by persons not commercially interested, directly or indirectly, in the sale of such drugs or devices: Provided, That whenever the Board determines that an advance in medical science has made any type of self-medication safe as to any of the diseases named above, the Board shall by regulation authorize the advertisement of drugs having curative or therapeutic effect for such disease, subject to such conditions and restrictions as the Board may deem necessary in the interests of public health: Provided further, That this section shall not be construed as indicating that self-medication for diseases other than those named herein is safe or efficacious.

Sec. 26. Regulations and Hearings. (a) The authority to promulgate regulations for the efficient enforcement of this Act is hereby vested in the Board.

(b) Hearings authorized or required by this Act shall be conducted by the Board or such officer, agent, or employee as the Board may designate for the purpose.

(c) The purpose of this Act being to promote uniformity with the Federal Act, the Board is hereby authorized to adopt, insofar as applicable, the regulations from time to time promulgated by the Secretary of Agriculture of the United States under the Federal Act.

(d) Except to the extent that the Board adopts the applicable regulations from time to time promulgated by the Secretary of Agriculture of the United States under the Federal Act the Board before promulgating any regulation contemplated by sections 11; 13 (j); 14; 18 (d), (f), (g) (exclusive of the proviso contained therein), or (h); or 25, shall give appropriate notice of the proposal and of the time and place for a public hearing to be held thereon not less than thirty days after the date of such notice. All regulations shall be promulgated by the Board by publishing the same in pamphlet or leaf form and supplying copies to all clerks of the

circuit court, prosecuting attorneys, and any citizen asking for the same. The regulation so promulgated shall become effective on a date fixed by the Board (which date shall not be prior to ninety days after its promulgation). Such regulation may be amended or repealed in the same manner as is provided for its adoption; except that in the case of a regulation amending or repealing any such regulation the Board, to such an extent as it deems necessary in order to prevent undue hardship, may disregard the foregoing provisions regarding notice, hearing, or effective date.

Sec. 27. Examinations and Investigations. (a) The Board shall cause the investigation and examination of food, drugs, devices and cosmetics subject to this Act. The Secretary or his duly authorized representative shall have the right (1) to take a sample or specimen of any such article, for examination under this Act, upon tendering the market price therefor to the person having such article in custody; and (2) to enter any place, establishment, or vehicle within this State, at reasonable times, for the purpose of taking a sample or specimen of any such article, for such examination.

(b) For the purpose of enforcing the provisions of this Act, pertinent records of any administrative agency of the State Government shall be open to inspection by the Secretary or his duly authorized representative.

Sec. 28. Records of Shipment. For the purpose of enforcing the provisions of this Act, carriers engaged in commerce, and persons receiving food, drugs, devices, or cosmetics in commerce or holding such articles so received, shall upon the request of an officer or employee duly designated by the Board permit such officer or employee, at reasonable times, to have access to and to copy all records showing the movement in commerce of any food, drug, device, or cosmetic, or the holding thereof during or after such movement, and the quantity, shipper, and consignee thereof; and it shall be unlawful for any such carrier or person to fail to permit such access to and copying of any such record so requested when such request is accompanied by a statement in writing specifying the nature or kind of food, drug, device, or cosmetic to which such request relates: Provided, That evidence obtained under this section shall not be used in a criminal prosecution of the person from whom obtained.

Sec. 29. Establishment Inspection. For the purpose of enforcing the provisions of this Act, the Secretary, or his duly authorized representative, is authorized (1) to enter, at reasonable times, any factory, warehouse, place of production, or establishment subject to this Act, or to enter any vehicle being used to transport or hold food, drugs, devices, or cos-

metics; and (2) to inspect, at reasonable times, such factory, warehouse, place of production, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, labeling, and advertisements therein.

Sec. 30. Publicity. (a) The Secretary may cause to be published from time to time reports summarizing all judgments, decrees, and court orders which have been rendered under this Act, including the nature of the charge and the disposition thereof.

(b) The Secretary may cause to be disseminated information regarding food, drugs, devices, or cosmetics in situations involving, in the opinion of the Secretary, imminent danger to health or gross deception of, or fraud upon, the consumer. Nothing in this section shall be construed to prohibit the Secretary from collecting, reporting, and illustrating the results of his examinations and investigations under this Act.

Sec. 31. Separability Clause. If any provision of this Act is declared unconstitutional, or the applicability thereof to any person or circumstances is held invalid, the constitutionality of the remainder of the Act and the applicability thereof to other persons and circumstances shall not be affected thereby.

Sec. 32. Interpretation. This Act and the regulations promulgated hereunder, insofar as applicable, shall be so interpreted and construed as to effectuate its general purpose to enact State legislation uniform with the Federal Act.

Sec. 33. Effective Date and Repeals. (a) This Act shall take effect twelve months after the date of its enactment, and all laws or parts of laws in conflict with this Act are hereby repealed effective upon such date: Provided, That whereas an emergency exists for the immediate effectiveness thereof the provisions of section 26 shall become effective on the passage of this Act, and thereafter the Board is authorized hereby to (1) conduct hearings and to promulgate regulations which shall become effective on or after the effective date of this Act as the Secretary shall direct, and Provided further, That sections 11, 14, 18 (j), 20, and 21 (a), and all other provisions of this Act to the extent that they may relate to the enforcement of such sections, shall take effect on the date of the passage of this Act, except that in the case of a cosmetic to which the proviso of section 21 (a) relates, such cosmetic shall not, prior to the ninetieth day after such date of enactment, be deemed adulterated by reason of the failure of its label to bear the legend prescribed in such proviso. Provided further, That nothing contained in this act shall be deemed to repeal any laws or parts of laws providing for a license insofar as consistent with the provisions of this Act.

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